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Coke

(b) a valve positioned in the housing in a flow cross section of the fluid drug, wherein the valve has a substantially circular cross section and contains a sealing lip pretensioned within the hollow portion of the housing.

Remarks

The above amendments and these remarks are submitted in response to the Office Action of December 30, 1999, in which the Examiner rejected claims 1-16 under 35 U.S.C. § 112, 2nd ¶, rejected claims 4 and 5 under 35 U.S.C. § 112, 1st ¶, rejected claims 1-3 and 6-16 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,827,244 to Boettger (the "Boettger patent"), and rejected claims 4 and 5 under 35 U.S.C. § 102(e) or 35 U.S.C. § 103 in view of the Boettger patent. Applicant has amended independent claim 1, and submits the following argument to overcome these rejections, and Applicant respectfully submits that the claims as amended are in condition for allowance.

I. Information Disclosure Statement

The Examiner stated that the information disclosure statement "fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance" of each patent that is not in the English language. Applicant respectfully submits that the translated Abstract submitted in the information disclosure statement satisfies the requirement under 37 CFR 1.56(c).

II. The Specification

Applicant has amended the Abstract to conform to the Examiner's reminder about the form of an Abstract. In response to the Examiner's request that the title be amended, Applicant

respectfully traverses the Examiner's requirement for a new title. The invention relates to a device for the metered administration of a fluid drug, and hence Applicant has not amended the title.

III. The Claims Are Patentable Over the Art of Record

A. Independent Claim 1

The Examiner rejected independent claim 1, as well as dependent claims 2-16, under 35 U.S.C. §112, 2nd ¶ as being indefinite for failing to point out and distinctly claim the subject matter of the invention. Applicant has amended claim 1 to remove the reference to "the flow," and Applicant therefore respectfully submits that this ground for rejection has been obviated. In addition, Applicant has removed the reference to "the front end," and Applicant submits that this ground for rejection has also been obviated.

The Examiner rejected claims 1-3 and 6-16 under §102(e) as being anticipated by the Boettger patent, stating that "Boettger teaches an IV infusion system maintaining a syringe and catheter in fluid communication and attached via a check valve. A sealing lip maintains the fluid communication." December 30, 1999 Office Action at 4.

The Boettger patent depicts a coupling assembly 10 having a pair of interconnectable threadably components 18 (a male component) and 20 (a female component). "Relative rotation of the two components [18, 20] . . . causes the threads 44 and 48 to matingly inter-engage and draw the female component 20 up into the male component 18. . . . Continued relative rotation of the two parts causes the valve stem 52 to be depressed by the cannula 30, opening the internal valve within the body 54 and establishing liquid flow communication between the body 54 and the interior chamber of the syringe 12." Boettger patent, Col. 5, ll. 49-61. Details of the

"internal valve within the body 54" are not disclosed in the Boettger patent. Based on this discussion from the Boettger patent cited above, it is clear that the device of the Boettger patent provides for a coupling device that may be manually rotated such that in one position it allows the flow of a liquid and in another position the liquid flow is shut off.

U.S. Patent No. 5,453,097 to Paradis (the "Paradis patent") was also cited by the Examiner. The Paradis patent discloses a "deformable elastomeric disk that is fixedly disposed between inlet and outlet members. The disk is deformable by pressure to permit flow through the inlet to the outlet, and a member is spaced from the disk for limiting the deformation thereof in the direction of pressure through said outlet to the disk." Paradis patent, Col. 4, ll. 30-35. As shown in Figure 4 of the Paradis patent, the member 12 is spaced from the disk 10d to limit deformation of the disk, and the disk will therefore not allow flow from the outlet through the disk to the inlet. As the Background of the Paradis patent explains, a purpose of the disk is to "prevent an emergence of fluid, because of blood pressure, from the valve connected to the cannula," or from the patient through the disk. Paradis patent, Col. 1, ll. 25-27.

A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. MPEP § 2131. All of the aspects of Applicant invention as claimed in amended independent claim 1 are not disclosed in the Boettger patent, Paradis patent, or in any other prior art of which Applicant is aware, and Applicant therefore submits that independent claim 1 is patentable over the art of record. In particular, independent claim 1 has been amended to state that the "valve permits flow of the fluid drug through the valve from the outlet to the injection needle when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug." Such a feature is disclosed in none of

the prior art of which Applicant is aware. Although the Boettger and Paradis patents may relate generally to flow control devices, neither patent seeks to permit flow through the valve "when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug." Applicant invention as claimed in claim 1, in contrast to the Paradis and Boettger patents, claims a device that allows for the flow of fluid through a valve when a certain pressure exists. Because Applicant invention as claimed in independent claim 1 contains at least this one feature that is not disclosed or suggested in any prior art reference of record, Applicant respectfully submits that this claim is in condition for allowance.

B. New Independent Claims 17, 23, and 24

New independent claim 17 claims a device for the metered administration of a drug. The device contains a housing and a valve, and "the housing pretensions the valve at a contact surface thereof against an aperture of a feed line through the housing to the valve." Such a device may be used to control the flow of the fluid drug such that the fluid drug will not flow through the device at a certain pressure level, but will flow through the device at certain higher pressure levels. Applicant respectfully submits that the none of the art of record discloses such a pretensioned valve and housing, and Applicant therefore submits that this claim is in condition for allowance. The Paradis patent, for example, does not disclose a pretensioned valve, but instead discloses a valve that is deformable by pressure to permit flow.

New independent claim 23 claims a device for the metered administration of a fluid drug. The device contains a housing, a connecting needle, a valve with a "sealing lip pretensioned around the second end of the connecting needle." Applicant respectfully submits that the none of the art of record discloses such a valve, connecting needle, and housing, and Applicant therefore

submits that this claim is in condition for allowance.

New independent claim 24, which also claims a device for the metered administration of a fluid drug, includes a housing and a valve that "contains a sealing lip pretensioned within the hollow portion of the housing." Applicant respectfully submits that none of the art of record disclose such a device having a valve with a sealing lip pretensioned within a hollow of the housing, and Applicant therefore submits that this claim is in condition for allowance. A notice of allowance is respectfully requested.

C. The Dependent Claims Are Patentable Over the Prior Art

Because each dependent claim incorporates all of the limitations of the independent claim from which it depends as well as additional limitations, the above arguments apply a fortiori to these claims. Thus, claims 2, 6-16, and 18-22 are also in condition for allowance. With respect to the Examiner's rejections of claims 4-5 under 35 U.S.C. §112, 1st ¶, Applicant notes that these claims have been canceled in this response, and this ground for rejection is therefore obviated.

IV. Conclusion

One independent claim in excess of three has been added in this amendment and response, requiring a fee payment of \$78, and one claim in excess of twenty has been added, requiring a fee payment of \$18. A petition for a three month extension (from March 30, 2000 until June 30, 2000) is submitted herewith, requiring a fee payment of \$870. The Office is hereby authorized to charge these fees, in the amount of \$966, to Deposit Account No. 04-1420.

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In view of the above amendments and preceding remarks, it is urged respectfully that claims 1-2 and 6-24 be allowed. However, if the Examiner believes that any issues remain unresolved, she is invited to telephone the undersigned to expedite allowance.

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Respectfully submitted,



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